

REMARKS

In the outstanding Office Action, the Examiner withdrew finality of the previous Office Action as well as the obviousness-type double patenting rejections of claims 1, 6, 8 and 9 of the present application. However, the Examiner upheld the previously raised §103 rejections against pending claims of the present application and stated that the arguments presented by Applicants in support of non-obviousness of such claims over the cited prior art references are not persuasive.

Specifically, the Examiner asserted that the Howard reference, which was submitted previously by the Applicants to show the mechanism of exfoliants, does not qualify as prior art because it was published after the filing date of the present application. Further, the Examiner asserted that the Madison reference, which was submitted previously by the Applicants to show the desquamation inhibitory effect of cholesterol sulfate, is not reliable because it only showed inhibition of desquamation at excess amounts of cholesterol sulfate and it stated that the mechanism by which such desquamation inhibition takes effect is still under investigation.

In response to the Examiner's dismissal of the previously submitted references, i.e., Howard and Madison, Applicants hereby submit two new references, both of which were published before the filing date of the present application, to support the previously presented arguments for non-obviousness of the pending claims of the present application over the cited prior art references. The first reference, Sato et al., "Cholesterol Sulfate Inhibits Proteases that are Involved in Desquamation of Stratum Corneum," THE JOURNAL OF INVESTIGATIVE DERMATOLOGY, Vol. 111, No. 2 Aug. 1998 (hereinafter "**Sato**"), is provided herein to show the known inhibitory effect of cholesterol sulfate on desquamation or cell dissociation from the stratum corneum sheet at various concentrations ranging from 0.01 mM to 10 mM. The second reference, International Patent Application No. WO 00/67722 published on November 16, 2000 (hereinafter "**WO 00/67722**"), is provided herein to show the known use of amino sugar as exfoliant to accelerate the natural desquamation process. Further, Applicants hereby submit English translations of the two prior art references cited by the Examiner in the outstanding Office Action.

Based on the newly submitted supporting references, Applicants respectfully traverse the Examiner's §103 rejections of claims 1 and 3-20 of the present application, as follows:

Non-Obviousness of Claims 1, 3, 5, 13 and 16-19 Over Abe '911 and Shimada

The Examiner has based her §103 rejections of claims 1, 3, 5, 13, and 16-19 on the reasoning that such claims are unpatentable over the combination of Abe et al., Japanese Patent Application No. 60-161911 (hereinafter “**Abe ‘911**”) with Shimada et al., Japanese Patent Application No. 59-013708 (hereinafter “**Shimada**”) and that it would be obvious to combine the teaching of **Abe ‘911** on using cosmetic compositions containing cholesterol sulfate for “improving dried skin, preventing aging skin, providing skin with wetting characteristics, softness and luster by promoting the water retention function of the skin” (see outstanding Office Action, page 5) with the teaching of **Shimada** on using cosmetic compositions containing N-acetyl amino sugars or their salts to “give smoothness and moist feeling to the skin, the amino sugars having an emollient effect, a skin activating effect and being capable of giving smooth feeling, springiness and luster to the skin” (see outstanding Office Action, page 6). The Examiner concludes that it would have been obvious to combine these two distinct compositions since they are taught by the prior art to be useful for the same purpose urging that the idea to combine them flows logically from their having been individually taught in the prior art, citing *In re Kerkhoven* (see outstanding Office Action, page 7).

However, in doing so, the Examiner has chosen to read the Abe ‘911 and Shimada references in vacuum while ignoring the underlying knowledge that one of ordinary skill in the art would have been expected to be aware of. Applicants hereby submit that this is not the appropriate approach in evaluating the obviousness of a claimed invention.

It has been well established that when challenge is made on the ground that the claimed invention would have been obvious, all evidence relevant to the obviousness-nonobviousness issue must be considered. *In re Sernaker*, 217 USPQ 1, 7 (Fed. Cir. 1983). Because virtually all inventions are combinations of old elements known in the art, it is insufficient for the Examiner to merely establish that the separate elements of the invention existed in the prior art. The Examiner must consider what the prior art as a whole would have suggested to one skilled in the art.

Environmental Designs, Ltd. v. Union Oil Company of California, 218 USPQ 865, 870 (Fed. Cir. 1983), citing *In re McLaughlin*, 170 USPQ 209, 212 (CCPA 1971). Specifically, the Examiner must view the beliefs of those in the field at the time of the invention. *Arkie Lures Inc. v. Gene Larew Tackle Inc.*, 43 USPQ2d 1294, 1297 (Fed. Cir. 1997).

In other words, the obviousness-nonobviousness issue should be determined on what one of ordinary skill in the art would have considered at the time of the invention, while viewing the prior art as a whole. In so doing, the skilled artisan would have been expected to ascertain what is already

known in the art about the ingredients individually disclosed by separate references, prior to combining such ingredients.

In the present case, although the **Abe '911** and **Shimada** references separately disclose the cosmetic use of cholesterol sulfate or a salt thereof and N-acetylamino sugars for improving skin appearance and feel, evidence also indicates that prior to the present invention, it was known in the art that cholesterol sulfate and N-acetylamino sugars achieve their respective skin care benefits through opposite mechanisms or modes of action on the stratum corneum layer of the skin.

Specifically, the **Sato** reference submitted herewith proves that prior to the present invention, cholesterol sulfate is known to inhibit or retard desquamation. Through various *in vivo* and *in vitro* tests, **Sato** clearly demonstrates that cholesterol sulfate has an inhibitory effect on desquamation or cell dissociation from the stratum corneum sheet, and that topical application of cholesterol sulfate functions to increase stratum corneum thickness. Further, the English translation of the **Abe '911** reference, which was cited by the Examiner to support the §103 rejections of the pending claims of the present application, confirms such desquamation inhibitory effect of cholesterol sulfate demonstrated by **Sato**. In Table 3 on page 66, the Abe '911 reference clearly shows that the skin of test subjects treated with compositions containing cholesterol sulfate has a lower exfoliation index value in comparison with skin treated with compositions without cholesterol sulfate, indicating that cholesterol sulfate retards or inhibits exfoliation or desquamation of corneal cells from the skin.

In the outstanding Office Action, the Examiner dismissed the previously submitted Madison reference on the basis that Madison only discloses inhibition of desquamation at excess amounts of cholesterol sulfate (see outstanding Office Action, page 24). However, the term “excess amounts” in Madison is not clearly defined, and it is incorrect for the Examiner to immediately jump into the conclusion that the amounts of cholesterol sulfate as used by the Abe '911 reference are not “excess” and are therefore insufficient to achieve the desquamation inhibitory effect. The newly submitted **Sato** reference clearly demonstrates that cholesterol sulfate is capable of retarding or inhibiting desquamation at various concentrations ranging from as low as 1 mM (equivalent to about 0.0488 wt%) to as high as 10 mM (equivalent to about 0.488 wt%), while the Abe '911 reference teaches use of cholesterol sulfate at concentrations ranging from about 0.01 to about 5 wt%. Therefore, the cholesterol sulfate concentrations as taught by the Abe '911 reference are sufficient to have an inhibitory effect on skin desquamation. This is further confirmed by the **Abe '911** reference itself, which discloses in Table 3 that topically application of compositions containing 0.5 wt% of

cholesterol sulfate is sufficient to cause retardation or inhibition of exfoliation or desquamation of corneal cells from the skin.

In the outstanding Office Action, the Examiner also alleged that the previously submitted Madison reference is not reliable because it fails to disclose the mechanism by which cholesterol sulfate inhibits desquamation (see outstanding Office Action, page 24). However, one can learn to use an ingredient without having to understand the exact mechanism by which such ingredient takes effect. For example, our ancestors have long ago learned to use certain herbs for treating certain disease without understanding the biological mechanisms by which such herbal medicines take effect. In the present case, the mere lack of understanding of the underlying biological mechanism would not have prevented one ordinarily skilled in the art from appreciating the fact that cholesterol sulfate has an inhibitory effect on skin desquamation.

Therefore, a person ordinarily skilled in the art would have readily taken into consideration of the desquamation inhibitory effect of cholesterol sulfate after reading **Sato** and **Abe '911**.

On the other hand, the newly submitted **WO 00/67722** reference discloses the use of N-acetylamino sugars as exfoliants for aiding skin desquamation or sloughing. Specifically, **WO 00/67722** states that exfoliation is a technique whereby dead skin cells are removed or sloughed from the skin surface to promote a healthier and more youthful appearance to the skin and that exfoliants function to break the bond holding individual squames together and allow them to detach and shed (see **WO 00/67722**, page 1, last paragraph). **WO 00/67722** demonstrates that at the time of the invention, amino sugars such as N-acetyl-D-glucosamine and N-acetyl-D-galactosamine were known exfoliants which enhance or accelerate the natural desquamation process when applied to the skin.

The references as cited hereinabove, i.e., **Sato**, **Abe '911** and **WO 00/67722** clearly reveal prior art knowledge about the opposite mechanisms of action through which cholesterol sulfate and N-acetylamino sugars achieve their respective skin care benefits. Thus, while both of the noted compositions as disclosed by **Abe '911** and **Shimada** were known to enhance the feel and appearance of the skin if applied individually, a person ordinarily skilled in the art would have known that such compositions act based on totally different and opposite mechanisms, and it is unlikely that one skilled in the art would have chosen to combine a compound known to retard or inhibit skin desquamation (i.e., cholesterol sulfate) with a compound known to enhance or accelerate skin desquamation (i.e., amino sugars). At best, one would have expected these two compounds not to yield a beneficial result, but to cancel each other out.

This alone would have led one of ordinary skill in the art **NOT** to combine such ingredients in the manner suggested by the Examiner. The totality of the prior art disclosure as described hereinabove not only fails to teach or suggest, but actually leads away from, combination of cholesterol sulfate or a salt thereof and exfoliants such as N-acetylamino sugars. In other words, a person ordinarily skilled in the art, i.e., a person who would have been aware of the opposite mechanisms of action by cholesterol sulfate and amino sugars, would not be motivated toward, but would be motivated against, combining cholesterol sulfate or a salt thereof with exfoliants such as N-acetylamino sugars, due to the likelihood that the effects of these two ingredients would cancel each other out and thereby defeat the very purposes of the **Abe '911** and **Shimada** references. In fact, not until Applicants' invention was it realized that the combination of these two types of active ingredients into a single composition would provide a beneficial result.

Based on the foregoing, Applicants submit that contrary to the Examiner's assertions in the outstanding Office Action, it would not have been obvious for a person ordinarily skilled in the art to combine the cholesterol sulfate or a salt thereof disclosed by the **Abe '911** reference and the N-acetylamino sugars disclosed by the **Shimada** reference. Consequently, claims 1, 3, 5, 13, and 16-19 of the present application are patentable over **Abe '911** and **Shimada**.

Non-Obviousness of Claim 4 Over Abe '911, Shimada, and Abe '314

In the outstanding Office Action, the Examiner finalized the previous rejection of claim 4 under 35 U.S.C. §103(a) as allegedly obvious over **Abe '911** in view of **Shimada**, as applied to claims 1, 3, 5, 13, and 16-19 above, and further in view of Japanese Patent Application Publication No. 05-051314 to Abe et al. (hereinafter "**Abe '314**").

Claim 4 depends directly from claim 3, which in turn depends from claim 1. Therefore, claim 4 incorporates all the limitations recited by claim 1, including the combination of cholesterol sulfate or a salt thereof and an exfoliant.

As discussed in the above section pertaining to claim 1, it would not have been obvious for one of ordinary skill in the art to combine the cholesterol sulfate or a salt thereof disclosed by **Abe '911** and the exfoliant (i.e., N-acetylamino sugar) disclosed by **Shimada**, and claim 1 is thereby patentably distinguished over **Abe '911** and **Shimada** by reciting a combination of cholesterol sulfate or a salt thereof and an exfoliant. **Abe '314** was filed after **Abe '911** by the same applicant, i.e., Kanebo Ltd. Specifically, **Abe '314** discloses uses of specific cholesterol sulfate salts, such as

calcium, magnesium, sodium, and potassium salts, for promoting the water retention function of skin, consistent with the teachings of **Abe '911** (see the English translation of **Abe '314**, paragraph [0007]). Nothing in **Abe '314** teaches or suggests use of the cholesterol sulfate salts in a manner different from that taught by **Abe '911**.

Therefore, **Abe '314** does not remedy the above-described deficiency of **Abe '911** and **Shimada** and thus cannot support the rejection against claim 4 of the present application.

Non-Obviousness of Claims 6-9 and 14-15 Over Abe '911, Shimada, and Bernstein

Claims 6-9 and 14-15 were rejected by the Examiner in the outstanding Office Action under 35 U.S.C. §103(a) as allegedly obvious over **Abe '911** in view of **Shimada**, as applied to claims 1, 3, 5, 13, and 16-19 above, and further in view of International Patent Application Publication No. WO90/01323 to Bernstein (hereinafter "**Bernstein**").

Claims 6-9 and 14-15 depend from claims 1 and 13, respectively, and therefore incorporate all the limitations recited by claims 1 and 13, including the combination of cholesterol sulfate or a salt thereof with an exfoliant or an amino sugar.

As discussed in the above section pertaining to claims 1 and 13, it would not have been obvious for one of ordinary skill in the art to combine the cholesterol sulfate or a salt thereof disclosed by **Abe '911** and the exfoliant or amino sugar (i.e., N-acetylamino sugar) disclosed by **Shimada**, and claims 1 and 13 are therefore patentably distinguished over **Abe '911** and **Shimada** by reciting a combination of cholesterol sulfate or a salt thereof and an exfoliant or amino sugar. **Bernstein** only discloses uses of fatty acids, such as arachidonic, linoleic, linolenic, palmitic, stearic, oleic and docosanoic acids, and sterols, such as cholesterol and cholesterol sulfate, for improving the protective water barrier of the stratum corneum layer of the skin and treating dry skin. Nothing in **Bernstein** teaches or suggests combination of cholesterol sulfate or a salt thereof with an exfoliant or amino sugar.

Therefore, **Bernstein** does not remedy the above-described deficiency of **Abe '911** and **Shimada** and thus cannot support the rejections against claims 6-9 and 14-15 of the present application.

Non-Obviousness of Claim 10 Over Abe '911, Shimada, and Kitada

The Examiner rejected claim 10 under 35 U.S.C. §103(a) as allegedly obvious over **Abe '911** in view of **Shimada**, as applied to claims 1, 3, 5, 13, and 16-19 above, and further in view of Japanese Patent Application Publication No. 10-017458 to Kitada (hereinafter “**Kitada**”).

Claim 10 directly depends from claim 1 and therefore incorporates all the limitations recited by claim 1, including the combination of cholesterol sulfate or a salt thereof with an exfoliant.

As discussed in the above section pertaining to claim 1, it would not have been obvious for one of ordinary skill in the art to combine the cholesterol sulfate or a salt thereof disclosed by **Abe '911** and the exfoliant (i.e., N-acetylamino sugar) disclosed by **Shimada**, and claim 1 is thereby patentably distinguished over **Abe '911** and **Shimada** by reciting a combination of cholesterol sulfate or a salt thereof and an exfoliant. **Kitada** only discloses use of a plant extract from *Salvia officinalis* L, which contains sclareolide, for improving the uniformity of skin and preventing skin darkness caused by aging. Nothing in **Kitada** teaches or suggests combination of cholesterol sulfate or a salt thereof with an exfoliant.

Therefore, **Kitada** does not remedy the above-described deficiency of **Abe '911** and **Shimada** and thus cannot support the rejection against claim 10 of the present application.

Non-Obviousness of Claim 11 Over Abe '911, Shimada, and Takahashi

The Examiner further rejected claim 11 under 35 U.S.C. §103(a) as allegedly obvious over **Abe '911** in view of **Shimada**, as applied to claims 1, 3, 5, 13, and 16-19 above, and further in view of Japanese Patent Application Publication No. 06-263627 to Takahashi et al. (hereinafter “**Takahashi**”).

Claim 11 directly depends from claim 1 and therefore incorporates all the limitations recited by claim 1, including the combination of cholesterol sulfate or a salt thereof with an exfoliant.

As discussed in the above section pertaining to claim 1, it would not have been obvious for one of ordinary skill in the art to combine the cholesterol sulfate or a salt thereof disclosed by **Abe '911** and the exfoliant (i.e., N-acetylamino sugar) disclosed by **Shimada**, and claim 1 is thereby patentably distinguished over **Abe '911** and **Shimada** by reciting a combination of cholesterol sulfate or a salt thereof and an exfoliant. **Takahashi** only discloses use of a plant extract from white birch, which contains protease inhibitors, for preventing skin aging, improving the stratum corneum, and imparting skin-beautifying effects. Nothing in **Takahashi** teaches or suggests combination of cholesterol sulfate or a salt thereof with an exfoliant.

Therefore, **Takahashi** does not remedy the above-described deficiency of **Abe '911** and **Shimada** and thus cannot support the rejection against claim 11 of the present application.

Non-Obviousness of Claim 12 Over Abe '911, Shimada, Kitada, and Takahashi

The Examiner rejected claim 12 under 35 U.S.C. §103(a) as allegedly obvious over **Abe '911** in view of **Shimada**, as applied to claims 1, 3, 5, 13, and 16-19 above, and further in view of **Kitada** and **Takahashi**.

Claim 12 directly depends from claim 1 and therefore incorporates all the limitations recited by claim 1, including the combination of cholesterol sulfate or a salt thereof with an exfoliant.

As discussed in the above section pertaining to claim 1, it would not have been obvious for one of ordinary skill in the art to combine the cholesterol sulfate or a salt thereof disclosed by **Abe '911** and the exfoliant (i.e., N-acetylamino sugar) disclosed by **Shimada**, and claim 1 is thereby patentably distinguished over **Abe '911** and **Shimada** by reciting a combination of cholesterol sulfate or a salt thereof and an exfoliant.

Further, as discussed hereinabove in sections pertaining to claims 10 and 11, nothing in the **Kitada** and **Takahashi** reference teaches or suggests combination of cholesterol sulfate or a salt thereof with an exfoliant. In other words, **Kitada** and **Takahashi** do not remedy the above-described deficiency of **Abe '911** and **Shimada** and thus cannot support the rejection against claim 12 of the present application.

Non-Obviousness of Claim 20 Over Abe '911, Shimada, Bernstein, Kitada and Takahashi

The Examiner rejected claim 20 under 35 U.S.C. §103(a) as allegedly obvious over **Abe '911** in view of **Shimada**, as applied to claims 1, 3, 5, 13, and 16-19 above, and further in view of **Bernstein**, as applied to claims 6-9 and 14-15 above, and further in view of **Kitada** and **Takahashi**.

Claim 20 directly depends from claim 19 and therefore incorporates all the limitations recited by claim 19, including the combination of cholesterol sulfate or a salt thereof with an amino sugar.

As discussed in the above section pertaining to claim 19, it would not have been obvious for one of ordinary skill in the art to combine the cholesterol sulfate or a salt thereof disclosed by **Abe '911** and the amino sugar disclosed by **Shimada**, and claim 19 is thereby patentably distinguished over **Abe '911** and **Shimada** by reciting a combination of cholesterol sulfate or a salt thereof and an amino sugar.

Further, as discussed hereinabove in the section pertaining to claims 6-9 and 14-15 and the sections pertaining to claims 10 and 11, nothing in the **Bernstein**, **Kitada**, and **Shimada** references teaches or suggests combination of cholesterol sulfate or a salt thereof with an amino sugar. In other words, the secondary references **Bernstein**, **Kitada**, and **Shimada** do not remedy the above-described deficiency of **Abe '911** and **Shimada** and thus cannot support the rejection against claim 20 of the present application.

Conclusion

Based on the foregoing, Applicants submit that claims 1-20 as currently pending in the present application are in condition for allowance. Accordingly, Applicants respectfully request the Examiner to issue a Notice of Allowance in favor of the Applicants.

Respectfully submitted,



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